REMARKS

This is a full and timely response to the non-final Official Action mailed **February 19, 2009** (the "Office Action" or "Action"). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Under the imposition of a previous Restriction Requirement, claims 6, 17-54, and 57-59 were withdrawn. To expedite the prosecution of this application, withdrawn claims 21-54 and 57-59 were cancelled previously without prejudice or disclaimer. The other withdrawn claims depend from elected claim 1 and remain in the application. Applicant will be entitled to rejoinder of those claims upon allowance of claim 1. MPEP § 821.04.

By the forgoing amendment, the specification and claims 1 and 7 have been amended. Additionally, original claims 12 and 13 have been cancelled without prejudice or disclaimer. Thus, claims 1, 3-5, 7-11, 15, 16 and 63-67 are currently pending for further action.

Double Patenting Rejection:

In the recent Office Action claims 1, 3-5, 7-16, and 63-67 were rejected under non-statutory obviousness-type double patenting in view of claims 1-9 of the commonly owned U.S. Patent No. 5,911,816. Applicant does not necessarily agree that the rejected claims overlap in scope with claims 1-9 of U.S. Patent No. 7,034,846. Nevertheless, to advance the prosecution of this application, Applicant has submitted herewith a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) or 1.321(d). Following entry of this terminal disclaimer, the double patenting rejection should be reconsidered and withdrawn.

Prior Art:

Rejections under 35 U.S.C. §102(b):

In the recent Office Action, a number of separate and alternative rejections of independent claims 1 and 7 were made under § 102(b) that focus on the same arguments in rejection of the various claims. For the sake of brevity, these rejections will be dealt with together. They are as follows:

1. Claims 1, 3-5, 7-8, 13, 15, and 67 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,653,996 to Hsu (hereinafter "Hsu").

2. Claims 1, 3-5, and 7-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,976,964 to Schlossmann et al. (hereinafter "Schlossmann").

3. Claims 1, 3, 5, 7, 8, 12, 13, and 15 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,958,378 to Waldrep et al. (hereinafter "Waldrep").

4. Claims 1, 3-5, 7, 8, 10-12, 15, 63, and 64 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,160,669 to Wallach et al. (hereinafter "Wallach").

For at least the following reasons, these rejections should be reconsidered and withdrawn.

Claims 1 and 7:

Claim 1 recites:

> A jettable solution comprising:
> a plurality of vesicles;
> a pharmaceutical payload encapsulated within each of said vesicles; and
> an edible liquid vehicle, said plurality of vesicles being stably dispersed in said edible vehicle;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

Support for the amendment to claim 1 can be found in Applicant's originally filed specification at, for example, paragraph [0049].

Similarly, claim 7 recites:

> A jettable solution comprising:
> a plurality of vesicles; and
> a pharmaceutical payload encapsulated within a central interior of each of said vesicles;
> wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

In contrast, Hsu, Schlossmann, Waldrep, and Wallach do not, individually or in combination, teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The Office Action concedes that Hsu, Schlossmann, Waldrep, and Wallach do not specifically teach the viscosity of the compositions of the jettable solution of claim 1, and, supposedly, claim 7. (Action, pp. 3, 6, and 7). As would be known of to one of skill in the art, and as explained in Applicant's specification, at paragraph [0049] and elsewhere, in order to be jettable, a composition must have characteristics that will allow it to be delivered given the pressures, temperatures and other parameters of an inkjet material dispenser while protecting the pharmaceutical payload. For example, for a solution to be "jettable" it must have a certain viscosity and surface tension. (*See e.g.,* Applicant's specification, paras. [0049] and [0059]).

Whether or not the claimed solution is "jettable" is of immense significance. Specifically, as described in Applicant's specification,

> The precise metering capability of the inkjet material dispenser (150) along with the ability to selectively emit the metered quantity of aqueous vesicle pharmaceutical (160) onto precise, digitally addressed locations makes the present system and method well suited for a number of pharmaceutical delivery applications. According to one exemplary embodiment, the precision and addressable dispensing provided by the present inkjet material dispenser (150) allows for one or more compositions to be dispensed on a single edible structure (170). According to this exemplary embodiment, a combination therapy may be produced in a customized dosage for a patient.

(Applicant's specification, para. [0054]).

Thus, with the claimed jettable composition, a prescribing physician can order "a customized dosage for a patient" that is then produced by a pharmacist with an inkjet material dispenser, similar to an inkjet printer. (*Id.*). Without the jettable solution of Applicant's invention, producing a customized dosage for each patient would be unreasonably expensive. (Applicant's specification, para. [0059]). Consequently, the patient may have to ingest a much larger, standardized dosage of a pharmaceutical than the patient actually needs.

The Office Action states that "it is the examiner's position, ***in the absence of showing otherwise***, that the compositions of Hsu [, Schlossmann, Waldrep, and Wallach] posses the claimed viscosity." (Action, pp. 3, 6, and 7). The Office Action further states that "it is still the examiner's position that Hsu's preparations are jettable and ***applicant has not shown that [to] be otherwise***." (Action, p. 5)(emphasis added).

However, Applicant wishes to point out that it is incumbent upon the ***Examiner*** to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. Thus, because the Examiner failed to identify, in Hsu, Schlossmann, Waldrep, or Wallach, a jettable solution wherein the jettable solution is jettable with an inkjet material dispenser, a prima facie case of anticipation has not been established.

Further, in contrast to the claimed subject matter, none of the cited prior art references teach or suggest the claimed jettable solution with a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter. This subject matter and its advantages are entirely outside the scope and content of the cited prior art.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on any of Hsu, Schlossmann, Waldrep, or Wallach of claims 1 and 7 and their dependent claims should be reconsidered and withdrawn.

Finally, with regard to claim 7, the Office Action fails to specifically address claim 7 or to indicate how or where the cited prior art teaches the specific subject matter of claim 7.

For at least these additional reasons, the rejection of claim 7 and its dependent claims should be reconsidered and withdrawn.

5. In the recent Office Action, claims 1-3, 8, 10-15, and 67 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,645,464 to Hainfeld (hereinafter "Hainfeld"). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Again, claim 1 recites:

> A jettable solution comprising:
> a plurality of vesicles;
> a pharmaceutical payload encapsulated within each of said vesicles; and
> an edible liquid vehicle, said plurality of vesicles being stably dispersed in said edible vehicle;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

In contrast, Hainfeld does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The Office Action states that "[o]ne of the modes of delivery taught by Hainfeld is inkjet delivery . . . ." (Action, p. 7). The relevant portion of Hainfeld teaches that "[m]etallocytes may be made smaller for some purposes, such as for better passage through

capillaries and small blood vessels, or better accumulation in breached blood brain barrier accompanying brain tumors, or leaky vasculature found in tumors, or optimizing size for endocytosis, ***ink jet delivery***, or other specialized applications." (Hainfeld, col. 11, ll. 49-54). However, Hainfeld does not teach or suggest that such "ink jet delivery" comprises a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter. In fact, this is ***the only portion of Hainfeld that discusses ink jet delivery***, and does so ***in passing without any detail as the particulars of the ink jet delivery process***.

Current U.S. patent law requires that "'[t]he identical invention must be shown in as complete detail as is contained in the ... claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." MPEP § 2131. Hainfeld does not teach or suggest the identical invention in as complete detail as contained in claim 1. Specifically, Hainfeld does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter. Thus, the Office Action has failed to establish a prima facie case of anticipation.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection based on Hainfeld of claim 1 and its dependent claims should be reconsidered and withdrawn.

Rejections under 35 U.S.C. §103(a):

1. In the recent Office Action, claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu ***or*** Schlossmann ***or*** Waldrep ***or*** Hainfeld. For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 16:

Claim 16 recites: "[t]he jettable solution of claim 1, further comprising approximately 25 % vehicle, approximately 2 % vesicle forming component, approximately 3 to 6 % pharmaceutical payload, and water." In contrast, Hsu, Schlossmann, Waldrep, and Hainfeld do not teach or suggest a jettable solution comprising approximately 25 % vehicle, approximately 2 % vesicle forming component, approximately 3 to 6 % pharmaceutical payload, and water.

The Office Action concedes that "[i]t is unclear from these references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload." (Action, p. 8). The Office Action further states that "[a]ssuming that the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts of the phospholipids to form required population of liposomes and suspend them in a suitable amount of vehicle." (*Id.*). Thus, the Office Action asserts that it would have been ***obvious to try*** varying amounts of the elements of the jettable solution of claim 16 to obtain a preferred composition. However, Applicant respectfully asserts that this would be considered improper "obvious to try" rationale in support of this obviousness rejection.

> The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at ***two kinds of error***. In some cases, what would have been 'obvious to try' would have been ***to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were***

> ***critical or no direction as to which of many possible choices is likely to be successful*** . . . . In others, what was 'obvious to try' was ***to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.***" *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.).

MPEP § 2145(emphasis added).

The prior art references cited here give no indication of which parameters are critical to jettability, nor do any of these references give direction as to which of the many possible choices is likely to lead to a successful jettable solution. Further, none of the cited prior art references give any guidance as to the particular form of the jettable solution or how to achieve it. Instead, the Office Action makes conclusory statements, without support in the cited references, in rejecting claim 16. Thus, the Office Action has applied insufficient reasoning to support an obviousness rejection.

Claim 16 recites a jettable solution comprising approximately 25 % vehicle, approximately 2 % vesicle forming component, approximately 3 to 6 % pharmaceutical payload, and water. This subject matter is clearly not taught or suggest by the cited prior art references.

The Supreme Court recently addressed the issue of obviousness in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). The Court stated that the *Graham v. John Deere Co. of Kansas City*, 383, U.S. 1 (1966), factors still control an obviousness inquiry. Under the analysis required by *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in

view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Hsu, Schlossmann, Waldrep, and Hainfeld, did not include the claimed subject matter, particularly a jettable solution comprising approximately 25 % vehicle, approximately 2 % vesicle forming component, approximately 3 to 6 % pharmaceutical payload, and water.

The differences between the cited prior art and the claimed subject matter are significant because the recitations of claim 16 provide for a more efficient, safe, and convenient means of distributing a pharmaceutical to a patient. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 16 under 35 U.S.C. § 103 and Graham. Therefore, the rejection of claim 16 should not be sustained.

2. In the recent Office Action, claim 65 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsu ***or*** Schlossmann ***or*** Waldrep ***or*** Wallach ***or*** Hainfeld, in view of U.S. Patent No. 4,608,211 to Handjani et al. (hereinafter "Handjani"). The rejection of claim 65 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1. Further, for at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 65:

Claim 65 recites: "[t]he jettable solution of claim 1, further comprising an antifoaming agent to prevent foaming of said solution." In contrast, Hsu, Schlossmann, Waldrep, Wallach, Hainfeld, and Handjani do not teach or suggest a jettable solution comprising an antifoaming agent that is effective "to prevent foaming of said solution."

The Office Action concedes that Hsu, Schlossmann, Waldrep, Wallach, and Hainfeld do not teach the recitations of claim 65. (Action, p. 9). Thus, the Office Action cites to Handjani and states that "Handjani shows the routine practice of adding an antifoaming agent in liposomal compositions (col. 4, lines 1015)." (Action, p. 9). As stated in previous responses, what Handjani actually teaches is that "an anti-foaming agent is introduced into the aqueous phase *to be encapsulated.*" (Handjani, col. 4, lines 1-15). Thus, Handjani teaches an antifoaming agent encapsulated in liposomal vesicles. Being encapsulated, the antifoaming agent cannot be effective "to prevent foaming of said solution" as claimed. Thus, none of the cited prior art references teach or suggest the claimed jettable solution comprising an antifoaming agent effective to "prevent foaming of said solution."

The Office Action further states that "it is common knowledge that an anti-foaming agent is used to prevent foaming and therefore, if there is a surfactant in the composition or the composition has foaming properties one should be using an anti-foaming agent." (Action, p. 9). "The examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being 'well-known' in the art. *In re Ahlert*, 424 F. 2d 1088, 165 USPQ 418, 420 (CCPA 1970). . . . If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position." M.P.E.P § 2144.03. Applicant respectfully asserts that it is not common knowledge that an anti-foaming agent is used in the jettable solution of claim 65 as demonstrated above.

Still further, the Office Action states that the proteins taught by Handjani are surfactants, and that the surfactants are anti-foaming agents. (Action, p. 10). The Office Action, again, has made an assertion without evidentiary support. "The examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert*, 424 F. 2d 1088, 165 USPQ

418, 420 (CCPA 1970). . . . If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position." M.P.E.P § 2144.03. Applicant respectfully traverses the Office Action's assumption that the proteins taught by Handjani are surfactants, and that the surfactants are anti-foaming agents, and requests that the Office provide support for this statement.

Finally, the Office Action asserts that because the process of hydrating lipids with an aqueous solution of glucose results in the presence of glucose in both the interior and outer aqueous mediums, and that similar distribution would occur in connection with proteins, that one skilled in the art would expect similar distribution of anti-foaming agents. (Action, p. 10). However, the Office Action does not point out in which references this subject matter is taught. Therefore, a prima facie case of obviousness has not been demonstrated.

Again, under the analysis required by *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Hsu, Schlossmann, Waldrep, Wallach, Hainfeld, or Handjani, did not include the claimed subject matter, particularly an antifoaming agent to prevent foaming of a jettable solution.

The differences between the cited prior art and the claimed subject matter are significant because the recitations of claim 65 provide for a means to prevent foaming within a jettable solution. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 65 under 35 U.S.C. § 103 and Graham.

3. In the recent Office Action, claims 66 and 67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wallach, in view of Schlossmann. The rejection of claims 66 and 67 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

4. In the recent Office Action, claims 1-3, 5, 7, 10-16, and 67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hainfeld. For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Claim 1 recites:

> A jettable solution comprising:
> ***a plurality of vesicles***;
> ***a pharmaceutical payload encapsulated within each of said vesicles***; and
> an edible liquid vehicle, said plurality of vesicles being stably dispersed in said edible vehicle;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

In contrast, Hainfeld does not teach or suggest a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within each of the vesicles. The Office Action states that "Hainfled . . . teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles ***which in turn attach*** (sic) ***to antibodies, peptides, nucleic acids (pharmaceutical payload)***." (Action, p. 11)(emphasis added). Hainfled

actually teaches the following with regard to the role of antibodies, peptides, nucleic acids in the system of Hainfled:

> The metal particles can passively or actively be delivered to the site of interest. For example, ***metal particles can fill a compartment, such as vasculature***, the bladder, or by injection to a region, ***or be additionally directed to specific sites by the coating on the metal particle with such directing substances such as antibodies, drugs, peptides, proteins, lipids, carbohydrates, nucleic acids, or other materials***.

(Hainfeld, col. 9, ll. 22-29)(emphasis added).

In other words, Hainfeld teaches that metal particles may be delivered to cells through use of a vasculature. Clearly, the metal particles cannot be interpreted as ***a pharmaceutical payload*** encapsulated within a plurality of vesicles.

Hainfeld also simply states that the metal particles may be simply coated with directing substances which may include antibodies, peptides, or nucleic acids. However, it is clear that this alternative embodiment of Hainfeld does not teach a pharmaceutical payload ***encapsulated within a plurality of vesicles***, but simply teaches attaching certain targeting moieties directly to the metal particles.

However, claim 1 recites a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within each of the vesicles. This subject matter is clearly outside the scope and content of the teachings of Hainfeld.

Further, Hainfeld does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The Office Action concedes that Hainfeld "does not teach how to prepare the liposomal compositions to be delivered through ink jet delivery," but that since liposomal

preparations are well known in the art it would have been obvious to use such techniques in ink jet delivery systems. (Action, p. 11). However, Applicant respectfully disagrees.

The Office Action states that "[o]ne of the modes of delivery taught by Hainfeld is inkjet delivery . . . ." (Action, p. 11). The relevant portion of Hainfeld teaches that "[m]etallocytes may be made smaller for some purposes, such as for better passage through capillaries and small blood vessels, or better accumulation in breached blood brain barrier accompanying brain tumors, or leaky vasculature found in tumors, or optimizing size for endocytosis, ***ink jet delivery***, or other specialized applications." (Hainfeld, col. 11, ll. 49-54). However, Hainfeld does not teach or suggest that such "ink jet delivery" comprises a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. In fact, this is ***the only portion of Hainfeld that discusses ink jet deliver y***, and does so ***in passing without any detail as the particulars of the ink jet delivery process or the composition of a solution that is to be jetted through an ink jet nozzle***.

However, claim 1 recites a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. This subject matter is clearly not taught or suggest by Hainfeld.

Again, under the analysis required by *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Hainfeld, did not include the claimed subject matter,

particularly a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within each of the vesicles and in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The differences between the cited prior art and the claimed subject matter are significant because the recitations of claim 1 provide for a more efficient, safe, and convenient means of distributing a pharmaceutical to a patient. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 1 under 35 U.S.C. § 103 and Graham. Therefore, the rejection of claim 1 and its dependent claims should not be sustained.

Claim 7:

Claim 7 recites:

> A jettable solution comprising:
> ***a plurality of vesicles***; and
> ***a pharmaceutical payload encapsulated within a central interior of each of said vesicles***;
> wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

In contrast, Hainfeld does not teach or suggest a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within a central interior of each of said vesicles.

As an initial matter, the Office Action fails to specifically address claim 7 or to indicate how or where the cited prior art teaches the specific subject matter of claim 7. For at least this reason, the rejection of claim 7 and its dependent claims should be reconsidered and withdrawn.

The Office Action states that "Hainfled . . . teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles ***which in turn attach*** (sic) ***to antibodies, peptides, nucleic acids (pharmaceutical payload)***." (Action, p. 11)(emphasis added).

Hainfled actually teaches the following with regard to the role of antibodies, peptides, nucleic acids in the system of Hainfled:

> The metal particles can passively or actively be delivered to the site of interest. For example, ***metal particles can fill a compartment, such as vasculature***, the bladder, or by injection to a region, ***or be additionally directed to specific sites by the coating on the metal particle with such directing substances such as antibodies, drugs, peptides, proteins, lipids, carbohydrates, nucleic acids, or other materials***.

(Hainfeld, col. 9, ll. 22-29)(emphasis added).

As argued above, Hainfeld teaches that metal particles may be delivered to cells through use of a vasculature. Clearly, the metal particles cannot be interpreted as ***a pharmaceutical payload*** encapsulated within a plurality of vesicles.

Further, as also argued above, Hainfeld also simply states that the metal particles may be simply coated with directing substances which may include antibodies, peptides, or nucleic acids, and does not teach a pharmaceutical payload ***encapsulated within a plurality of vesicles***, but simply teaches attaching certain targeting moieties directly to the metal particles.

However, claim 7 recites a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within a central interior of each of said vesicles. This subject matter is clearly outside the scope and content of the teachings of Hainfeld.

Further, Hainfeld does not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The Office Action concedes that Hainfeld "does not teach how to prepare the liposomal compositions to be delivered through ink jet delivery," but that since liposomal preparations are well known in the art it would have been obvious to use such techniques in ink jet delivery systems. (Action, p. 11). However, Applicant respectfully disagrees.

The Office Action states that "[o]ne of the modes of delivery taught by Hainfeld is inkjet delivery . . . ." (Action, p. 11). The relevant portion of Hainfeld teaches that "[m]etallocytes may be made smaller for some purposes, such as for better passage through capillaries and small blood vessels, or better accumulation in breached blood brain barrier accompanying brain tumors, or leaky vasculature found in tumors, or optimizing size for endocytosis, ***ink jet delivery***, or other specialized applications." (Hainfeld, col. 11, ll. 49-54). However, Hainfeld does not teach or suggest that such "ink jet delivery" comprises a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. In fact, this is ***the only portion of Hainfeld that discusses ink jet deliver y***, and does so ***in passing without any detail as the particulars of the ink jet delivery process or the composition of a solution that is to be jetted through an ink jet nozzle***.

However, claim 7 recites a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. This subject matter is clearly not taught or suggest by Hainfeld.

Again, under the analysis required by *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Hainfeld, did not include the claimed subject matter, particularly a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within each of the vesicles and in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The differences between the cited prior art and the claimed subject matter are significant because the recitations of claim 7 provide for a more efficient, safe, and convenient means of distributing a pharmaceutical to a patient. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 1 under 35 U.S.C. § 103 and Graham. Therefore, the rejection of claim 7 and its dependent claims should not be sustained.

5. In the recent Office Action, claims 1-3, 5, 7-16, and 63-67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,911,816 to Gore (hereinafter

"Gore") in view of Hainfeld. For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claims 1 and 7:

Again, claim 1 recites:

> A jettable solution comprising:
> a plurality of vesicles;
> ***a pharmaceutical payload encapsulated within each of said vesicles***; and
> an edible liquid vehicle, said plurality of vesicles being stably dispersed in said edible vehicle;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added),

Similarly, claim 7 recites:

> A jettable solution comprising:
> a plurality of vesicles; and
> ***a pharmaceutical payload encapsulated within a central interior of each of said vesicles***;
> wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane;
> ***in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser*** to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

(Emphasis added).

In contrast Gore, Hainfeld, and Schlossmann do not teach or suggest a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The Office Action concedes that Hainfeld "does not teach how to prepare the liposomal compositions to be delivered through ink jet delivery," but that since liposomal preparations are well known in the art it would have been obvious to use such techniques in ink jet delivery systems. (Action, p. 11). However, Applicant respectfully disagrees.

The Office Action states that "[o]ne of the modes of delivery taught by Hainfeld is inkjet delivery . . . ." (Action, p. 11). The relevant portion of Hainfeld teaches that "[m]etallocytes may be made smaller for some purposes, such as for better passage through capillaries and small blood vessels, or better accumulation in breached blood brain barrier accompanying brain tumors, or leaky vasculature found in tumors, or optimizing size for endocytosis, ***ink jet delivery***, or other specialized applications." (Hainfeld, col. 11, ll. 49-54). However, Hainfeld does not teach or suggest that such "ink jet delivery" comprises a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. In fact, this is ***the only portion of Hainfeld that discusses ink jet deliver y***, and does so ***in passing without any detail as the particulars of the ink jet delivery process or the composition of a solution that is to be jetted through an ink jet nozzle***.

However, claims 1 and 7 recite a jettable solution in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser. This subject matter is clearly not taught or suggest by Hainfeld.

Further, the Office Action states that "Schlossmann teach[es] that the vesicular compositions containing drugs can be prepared . . . ." (Action, p. 12). However, this is incorrect. Schlossmann actually teaches away from the recitations of claim 1 and 7.

Specifically, Schlossmann teaches

> ***The dihydropyridines are dispersed in the membrane of the liposomes***. By liposomes there are understood artificially prepared vesicles, the membrane material of which chiefly consists of naturally occurring membrane components, such as phospholipids. ***If a compound is lipid-soluble, like the dihydropyridine derivatives, it can be incorporated in the lipid membrane, in contrast to water-soluble substances, which are enclosed in the aqueous inner volume of the vesicles on preparation of the liposomes***.

(Emphasis added).

In other words, Schlossmann teaches that the dihyropyridines are dispersed in the membrane of a liposome and that such dihyropyridines are not water-soluble, thus precluding them from being "enclosed in the aqueous inner volume of the vesicles."

In contrast, claims 1 and 7 recite a jettable solution comprising a pharmaceutical payload encapsulated ***within each of said vesicles*** or ***within a central interior of each of said vesicles***. Thus, Schlossmann clearly teaches away from the recitations of clam 1 and 7.

Applicant notes that it is improper to combine references where the references teach away from their combination. (In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). This principle was cited with approval in the recent Supreme Court decision, *KSR*. The Supreme Court in *KSR* discussed in some detail *United States v. Adams*, 383 U.S. 39 (1966), stating in part that in that case, "[t]he Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." Accordingly, it remains improper to combine references where the references teach away from their combination. Thus, it would be improper to combine the presently cited prior art references.

Again, under the analysis required by *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the

claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Hainfeld, did not include the claimed subject matter, particularly a jettable solution comprising a plurality of vesicles, and a pharmaceutical payload encapsulated within each of the vesicles or within a central interior of each of said vesicles, and in which said jettable solution comprises a viscosity of less than 5 centipoise, and a surface tension between approximately 25 and 60 dynes per centimeter such that said jettable solution is jettable with an inkjet material dispenser.

The differences between the cited prior art and the claimed subject matter are significant because the recitations of claims 1 and 7 provide for a safe, efficient, and convenient means of delivering a specific dosage of a pharmaceutical to a patient . Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claims 1 and 7 under 35 U.S.C. § 103 and Graham. Therefore, the rejection of claims 1 and 7 and their independent claims should not be sustained.

Conclusion:

In view of the foregoing arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue, or comment in the Office Action does not signify agreement with or concession of that rejection, issue, or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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/Steven L. Nichols/
Steven L. Nichols
Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095

(801) 572-8066
(801) 572-7666 (fax)